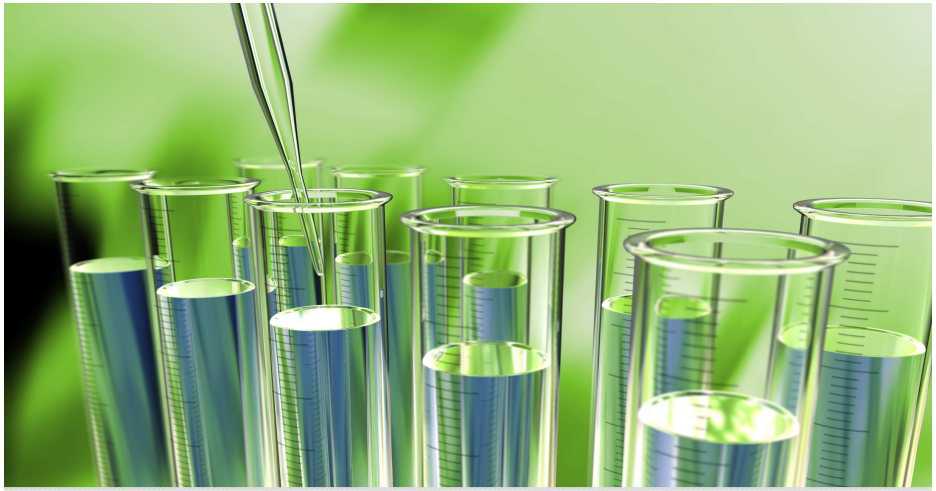

## CMA Testing and Certification Laboratories

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Implementation and Support Programme to deal with the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

TID SDF Project (Ref. No.: D09 002 006)

# IUCLID 5 WORKSHOP

17th December, 2010

Part 3

香港中華廠商聯合會 The Chinese Manufacturers' Association of Hong Kong

CMA Testing and Certification Laboratories 廠商會檢定中心

香港科技大學 HONG KONG UNIVERSITY OF SCIENCE & TECHNOLOGY

HKQAA HONG KONG QUALITY ASSURANCE AGENCY 香港品質保證局

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## Agenda

- **Preparing a registration dossier with IUCLID 5**
- **Import – Export**
- **Advanced tools**
- **Submit a dossier**

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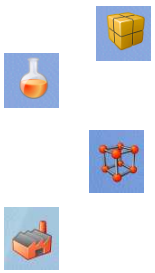
## What is a registration dossier?

### ► Dossier Definition & Characteristics

- a copy of selected data elements from the different IUCLID elements, such as:
  - Substance
  - Template
  - Category
  - Reference substance
  - Legal entity



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# What is a registration dossier?

## ► Dossier Definition & Characteristics

- Stored in the IUCLID 5 database
- **Read-only** snapshot of underlying data. Cannot be edited
- Unique identification number ("Dossier UUID") in addition to original UUIDs of each individual record
- Print to HTML feature
- Export feature



# What is a registration dossier?

## ► Dossier Definition & Characteristics

- Administrative Information:
  - Name of the Dossier (user-defined)
  - Dossier submission remark
  - Type of submission
  - Specific information for Dossier registration
- Ownership protection option:
  - Prevents Dossier ESRs/ESSs records from being copied

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# What is a registration dossier?

**Requirements are defined in Art. (10) of the REACH proposal**

- Technical dossier
  - company identity & substance identity
  - manufacture & uses – guidance on safe use - C&L - exposure information if applicable
  - study summaries - robust study summaries - proposals for testing
  - various statements
- Chemical safety report (>10 tonnes)
- Technical dossier: database format
  - **Data are filled in a structured format in the IUCLID database**
- Chemical safety report: document (e.g. MS Word);
  - **Document created and edited outside IUCLID**

One single package to be submitted to Agency

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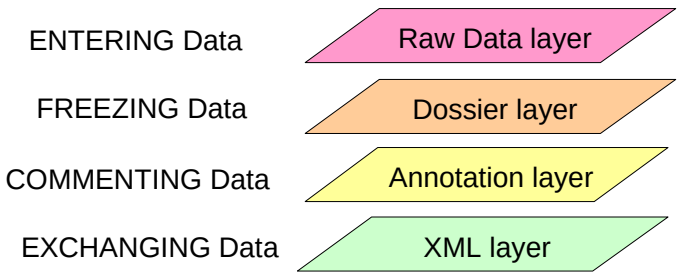
# Data Layer

## ► IUCLID 5: Raw Data/Dossier data/Annotations

- Multiple data layers in IUCLID 5

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# Data Layer

## ► IUCLID Data Layers

- Raw Data Layer
  It's where the information is stored. All the information entered into IUCLID5 is stored here and can be here modified, deleted or updated

- Dossier Layer
  It contains read-only data. The Dossier is a snapshot of a subset of the raw data selected by the user.
  Dossiers cannot be modified!



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# Data Layer

## ► IUCLID Data Layers

- Annotations
  All data objects can have annotations attached. The annotations are stored on a separate layer and each annotation cannot exist on its own (i.e. it needs a parent object like an endpoint study or a substance)

- XML
  Both data and dossiers can be exported in XML format by using IUCLID5.
  This happens in particular when:
  - Submitting Dossiers to the ECHA
  - exchanging data between SIEF members

  Exported IUCLID5 files have the extension .i5z, which is just a compressed collection of XML files.



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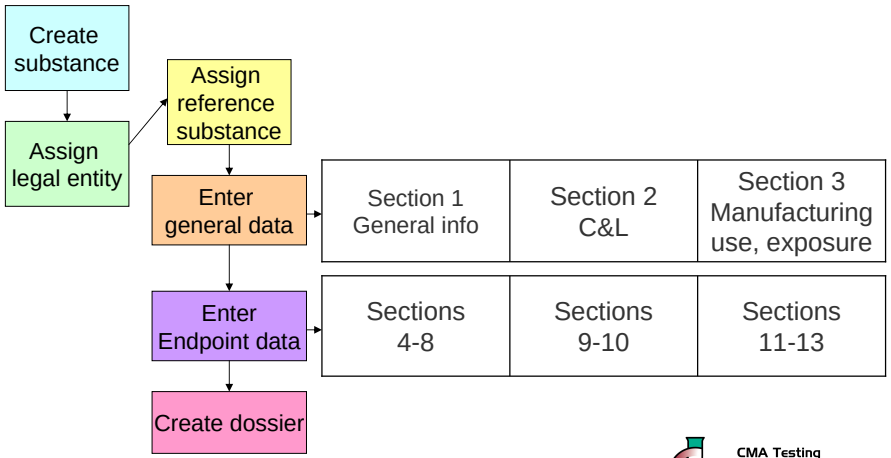
# Creating Dossier

## ► Creating a Dossier



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# Creating Dossier

## ► Adding a new substance

- Logon as appropriate user – e.g. technical
- Add new substance
- Find substance in reference substance inventory
- Add physical/chemical property data
- Add end point study data
- Create dossier
- Print dossier



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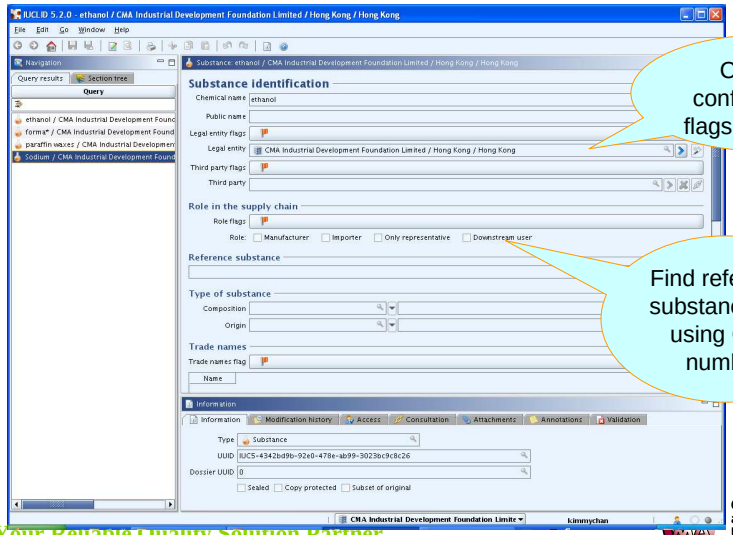
# Input substance info.



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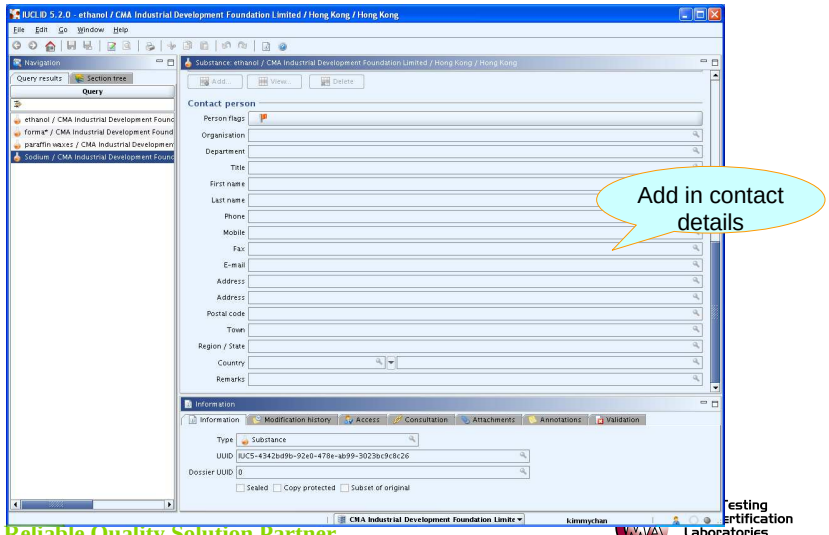
# Add-in contact info.



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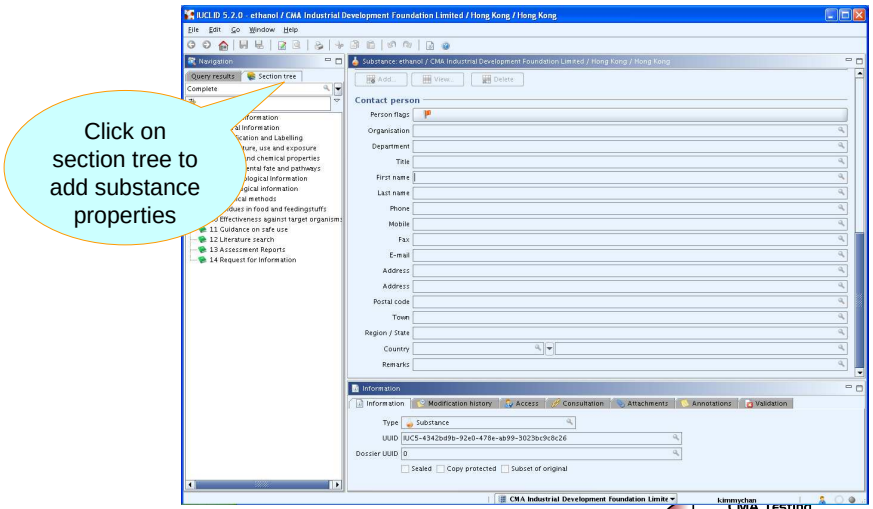
# Section tree



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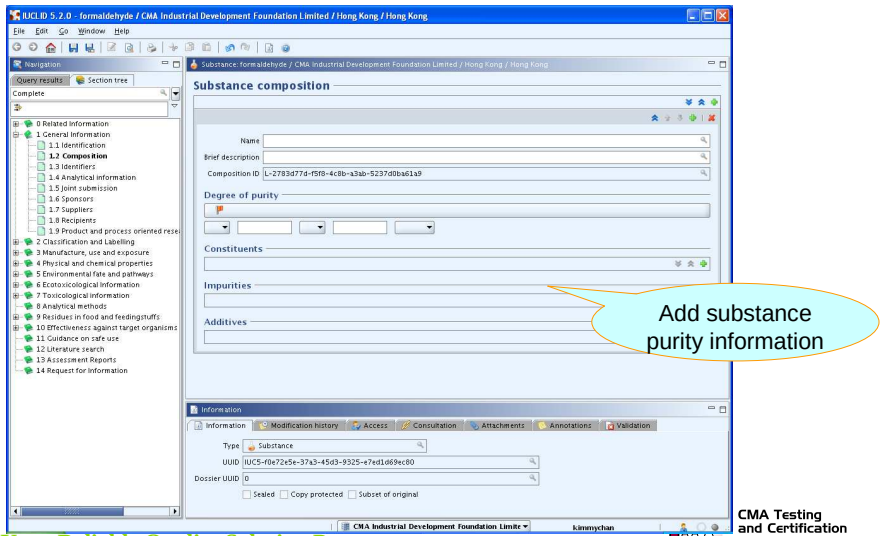
# Substance composition



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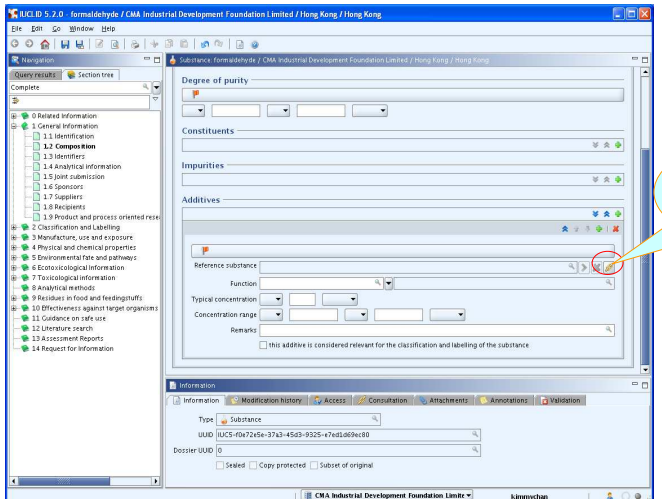
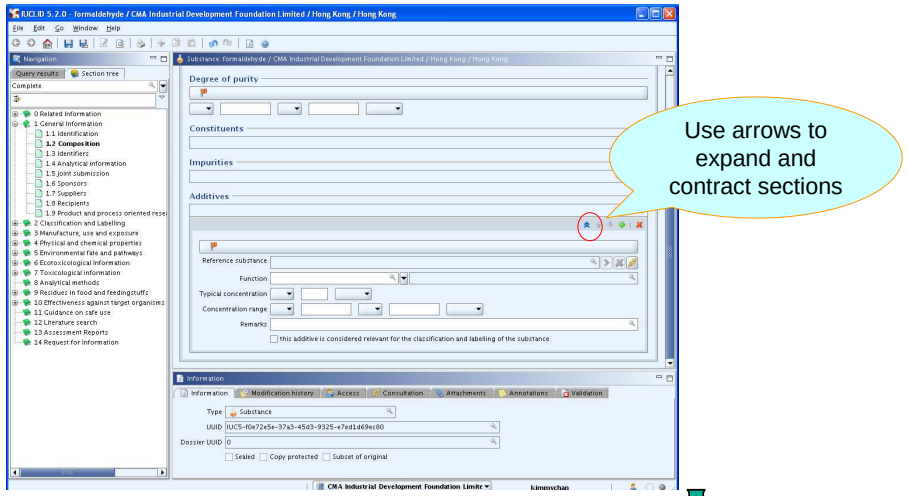
# Adding an additional constituent



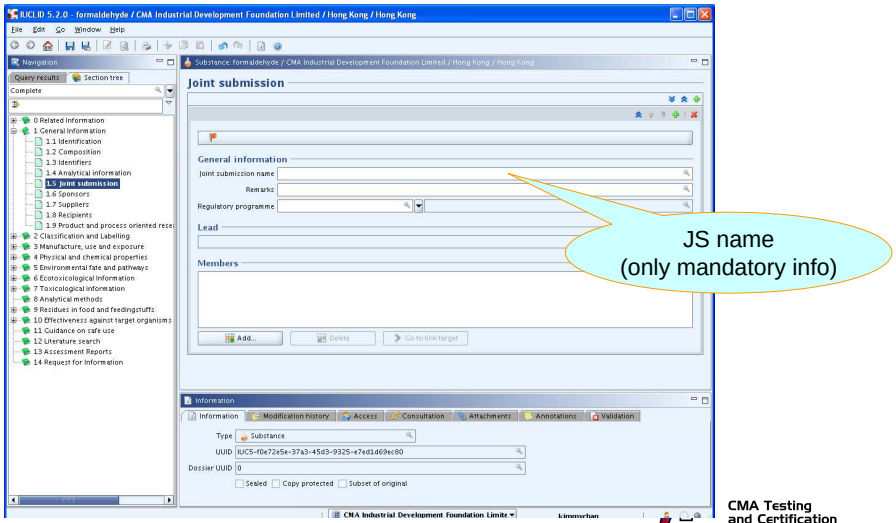



# Expanding/contracting sections



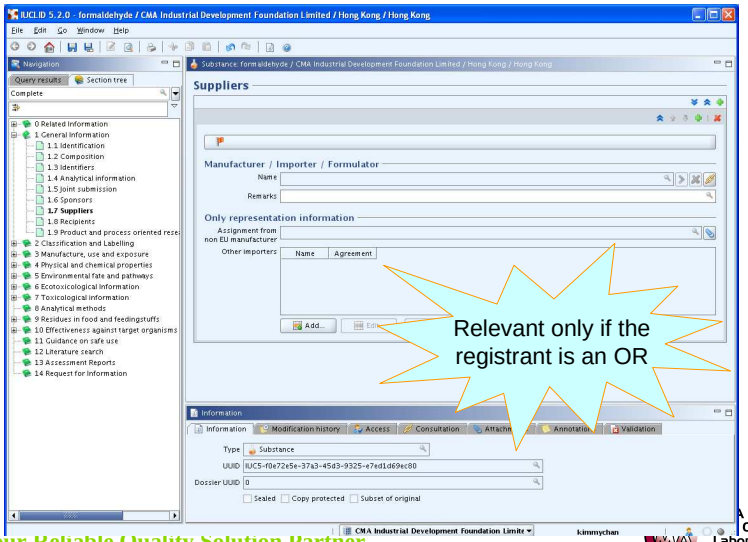



# Joint submission

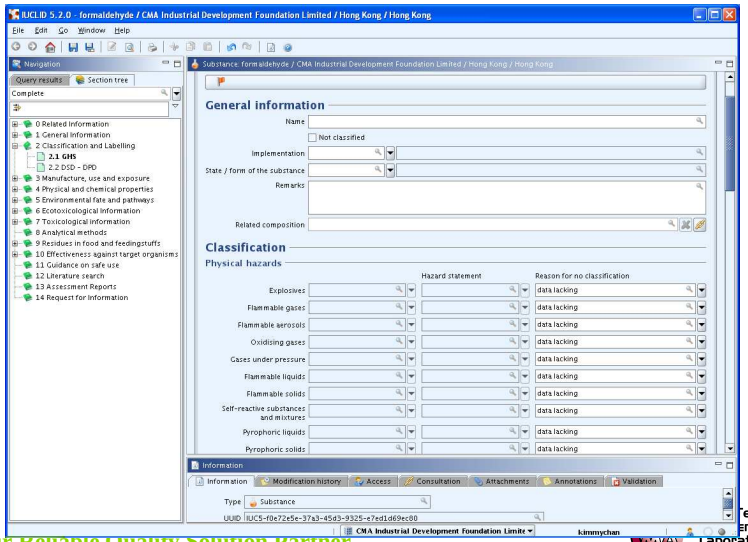





# Suppliers

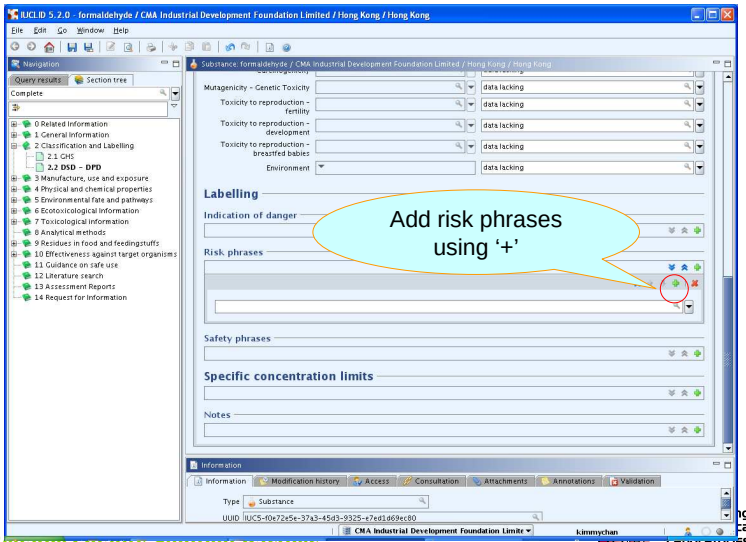


# Adding CLP information


IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
General information
Classification
Physical hazards

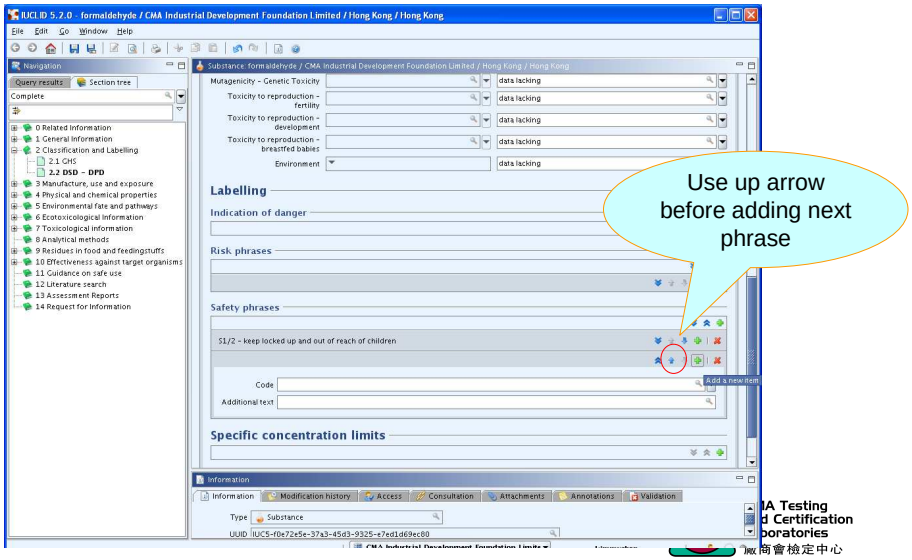


# Adding DSD-DPD information


IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
Add risk phrases using '+'
Labelling
Risk phrases
Safety phrases
Specific concentration limits
Notes

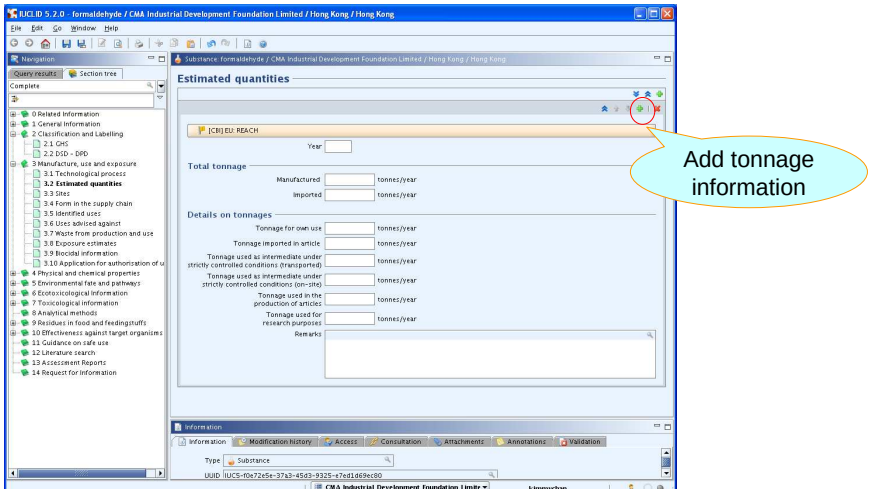


# Risk and Safety phrases

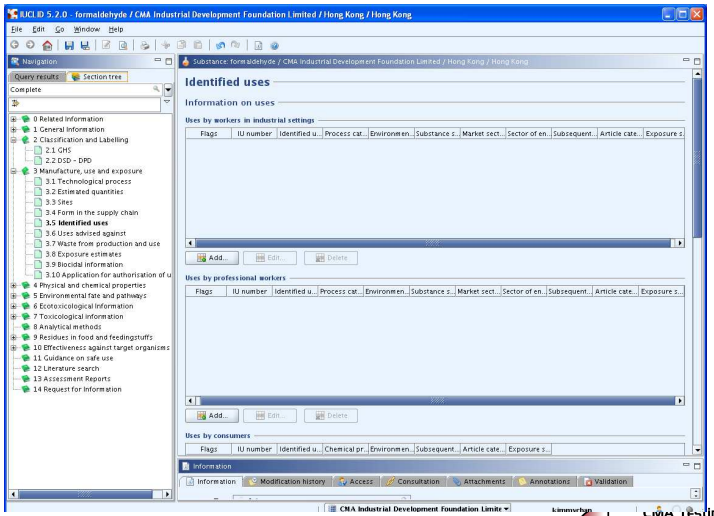

IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
Use up arrow before adding next phrase
Labelling
Risk phrases
Safety phrases
S1/2 - keep locked up and out of reach of children
Specific concentration limits



# Manufacture, use and exposure


IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
Estimated quantities
Add tonnage information
Total tonnage
Details on tonnages

# How to report identified uses


IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
Identified uses
Information on uses
Uses by workers in industrial settings
Uses by professional workers
Uses by consumers



# Sections 4-13: substance endpoint data

- The Sections 4-13 of IUCLID represent the format of the Technical Dossier as defined by Article 10 of REACH legislation.
- The Dossier must include the information specified in the Annexes VII to XI of REACH.



# Endpoints

► **An ENDPOINT is an information requirement of data point regarding a substance:**

- Physico-chemical properties
- Environmental date and behavior
- Ecotoxicological information
- Toxicological information
- Other specific information (e.g. effectiveness against a target organism)

Additional information is provided, like:

- Guidance on safe use
- Information on literature search
- Attachment (e.g. assessment reports)



# Endpoints

- Section 4: Physico-chemical properties
  melting poin, density, vapour pressure, etc.
- Section 5: Environmental fate and pathways
  stability, biodegradation, bioaccumulation, transport and distribution information, monitoring information
- Section 6: Ecotoxicological information
  aquatic and terrestrial toxicity, biological effects, degradation products

# Endpoints

- Section 7: Toxicological information
  toxicokinetics, acute toxicity, genetic toxicity, carcinogenicity etc.
- Section 8: Analytical methods
  data on analytical methods for a substance in different matrixes (e.g. air, soil, biological tissues)
- Section 9: Residues in food and feedingstuffs
  data on residues in food and feedingstuffs (for pesticides and biocides)



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# Endpoints

- Section 10: Effectiveness against target organisms
  only for substances with intended biocide properties
- Section 11: Guidance on safe use
  data first aid measures, safe use guidance, fire-fighting measures, handling, storage and transport measures, personal protection etc.
- Section 12: Literature search
  details on any literature search can be here provided
- Section 13: Assessment reports
  the assessment reports are attached to this section



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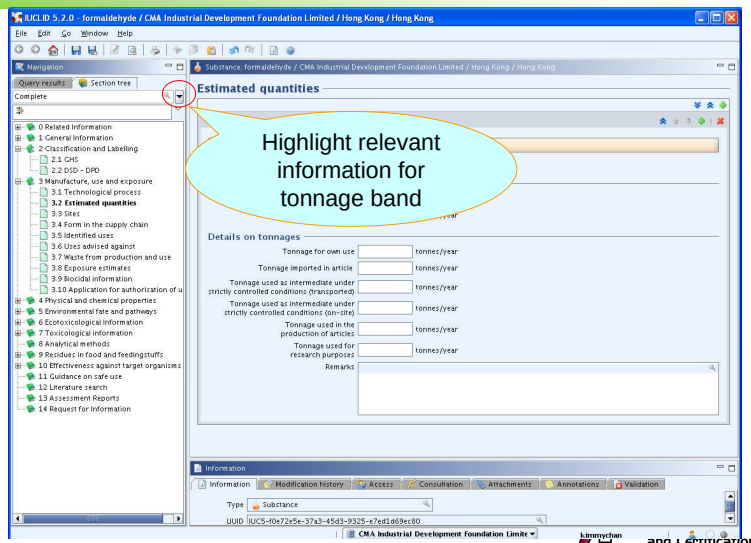
# Displaying information relevant for tonnage band


IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
Estimated quantities
Highlight relevant information for tonnage band
Details on tonnages



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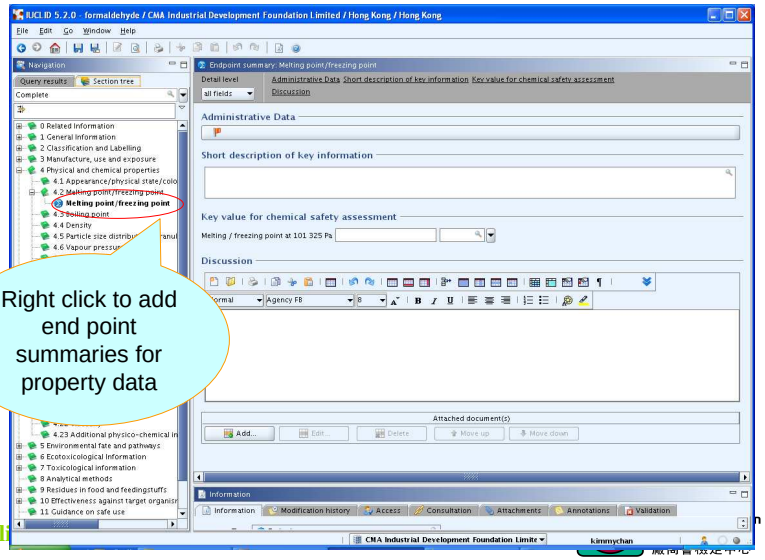
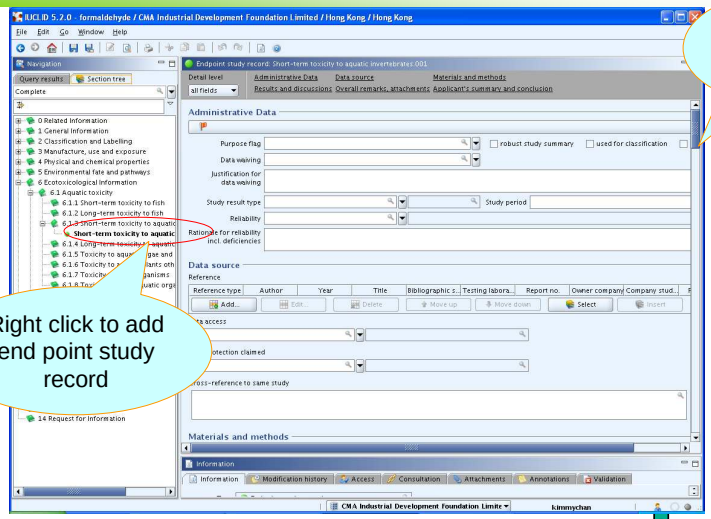
# Adding physical and chemical properties


IUCLID 5.2.0 - formaldehyde / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
Right click to add end point summaries for property data
Administrative Data
Short description of key information
Key value for chemical safety assessment
Discussion

# Adding an end point study record



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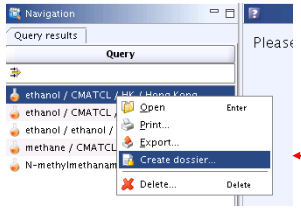
# Dossier

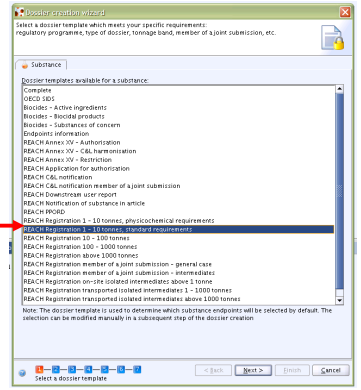
## ► Creating a Dossier




Select **Create dossier** from the shortcut menu (from a substance or Category module)

Follow the *Dossier Creation Wizard* that will guide you through the process:

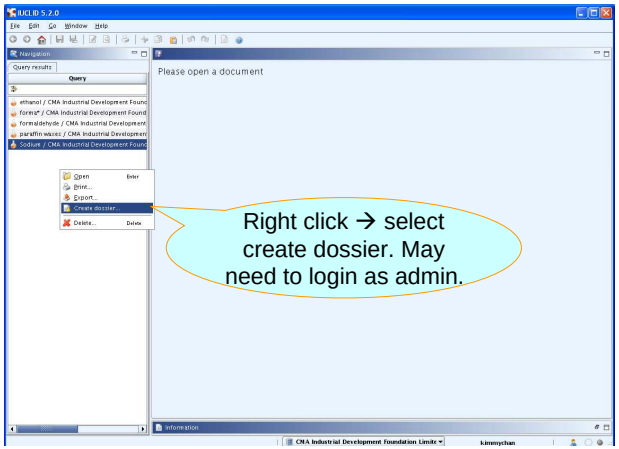
- *Select a Dossier template*


Dossier creation wizard
Substance
Dossier templates available for a substance:
Complete
OECD SIDS
Biocides – Active ingredients
Biocides – Biocidal products
Biocides – Substances of concern
Endpoints information
REACH Annex XV – Authorisation
REACH Annex XV – C&L harmonisation
REACH Annex XV – Restriction
REACH Application for authorisation
REACH C&L notification
REACH C&L notification member of a joint submission
REACH Downstream user report
REACH Notification of substance in article
REACH PPORD
REACH Registration 1 – 10 tonnes, physicochemical requirements
REACH Registration 1 – 10 tonnes, standard requirements
REACH Registration 10 – 100 tonnes
REACH Registration 100 – 1000 tonnes
REACH Registration above 1000 tonnes
REACH Registration member of a joint submission – general case
REACH Registration member of a joint submission – intermediates
REACH Registration on-site isolated intermediates above 1 tonne
REACH Registration transported isolated intermediates 1 – 1000 tonnes
REACH Registration transported isolated intermediates above 1000 tonnes
Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation
Select a dossier template
< Back
Next >
Finish
Cancel



# Dossier

## ► Creating a dossier



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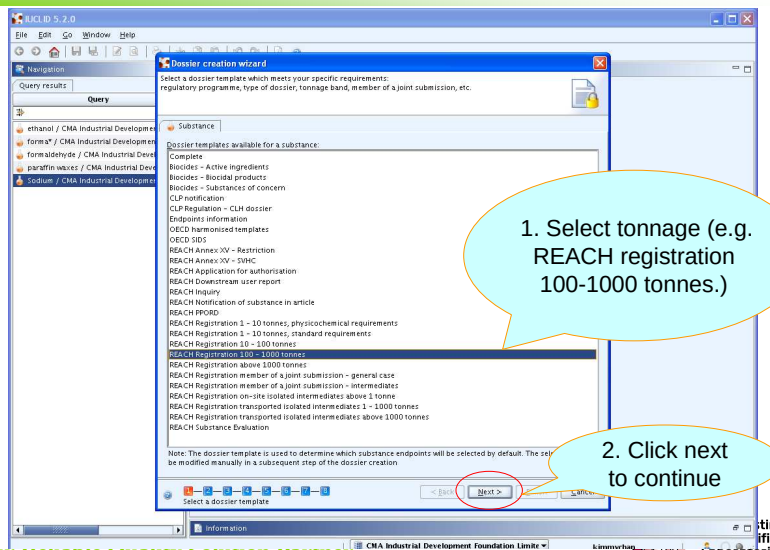
# Dossier output page 1


Dossier creation wizard
Select a dossier template which meets your specific requirements:
regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.
Substance
Dossier templates available for a substance:
Complete
Biocides – Active ingredients
Biocides – Biocidal products
Biocides – Substances of concern
CLP notification
CLP Regulation – CLH dossier
Endpoints information
OECD harmonised templates
OECD SIDS
REACH Annex XV – Restriction
REACH Annex XV – SVHC
REACH Application for authorisation
REACH Downstream user report
REACH Inquiry
REACH Notification of substance in article
REACH PPORD
REACH Registration 1 – 10 tonnes, physicochemical requirements
REACH Registration 1 – 10 tonnes, standard requirements
REACH Registration 10 – 100 tonnes
REACH Registration 100 – 1000 tonnes
REACH Registration above 1000 tonnes
REACH Registration member of a joint submission – general case
REACH Registration member of a joint submission – intermediates
REACH Registration on-site isolated intermediates above 1 tonne
REACH Registration transported isolated intermediates 1 – 1000 tonnes
REACH Registration transported isolated intermediates above 1000 tonnes
REACH Substance Evaluation
Select a dossier template
Next >
1. Select tonnage (e.g. REACH registration 100-1000 tonnes.)
2. Click next to continue



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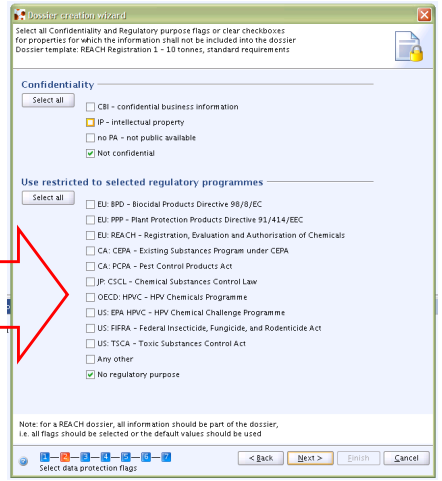
# Dossier

## ► Creating a Dossier

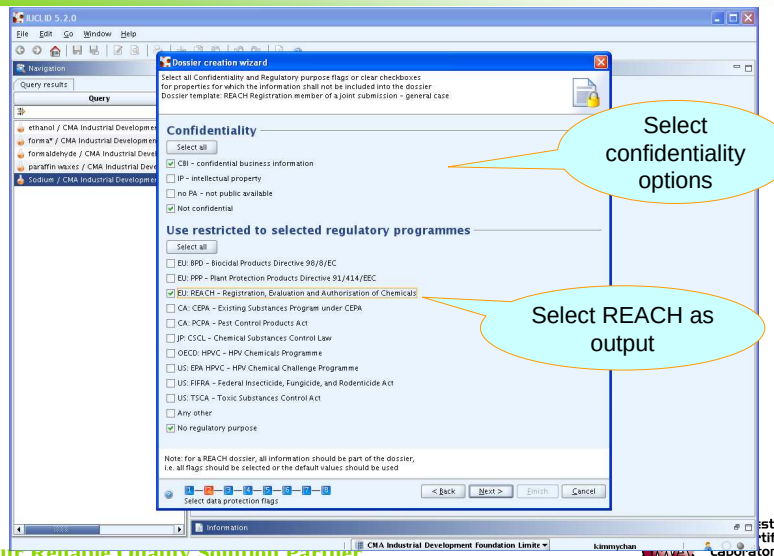
- Specify the Confidentiality Flags and Regulatory Purpose Flags, in order to filter the data that you want to be included into the Dossier

**Note:** for a REACH Dossier, all information should be part of the dossier, I.e. all flag should be selected or the default values should be used






# Dossier output page 2

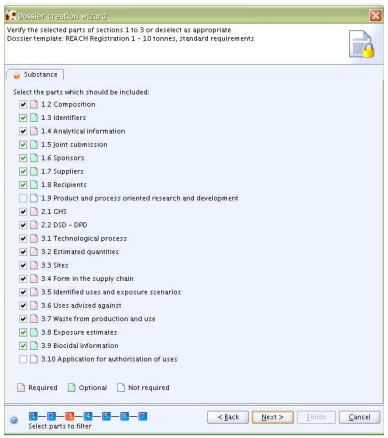





# Dossier

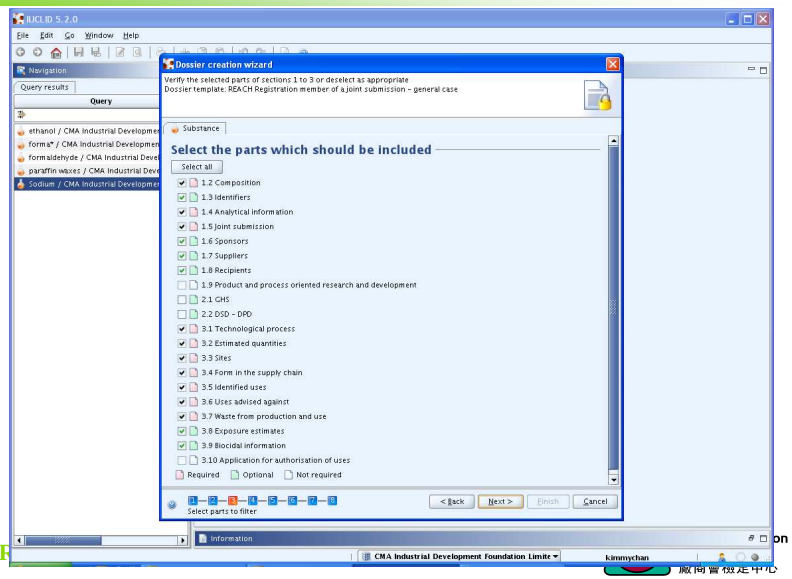
## ► Creating a Dossier

- Make a pre-selection of data to be included in the Dossier
- Validate the Dossier completeness
- Enter administrative data (optional)

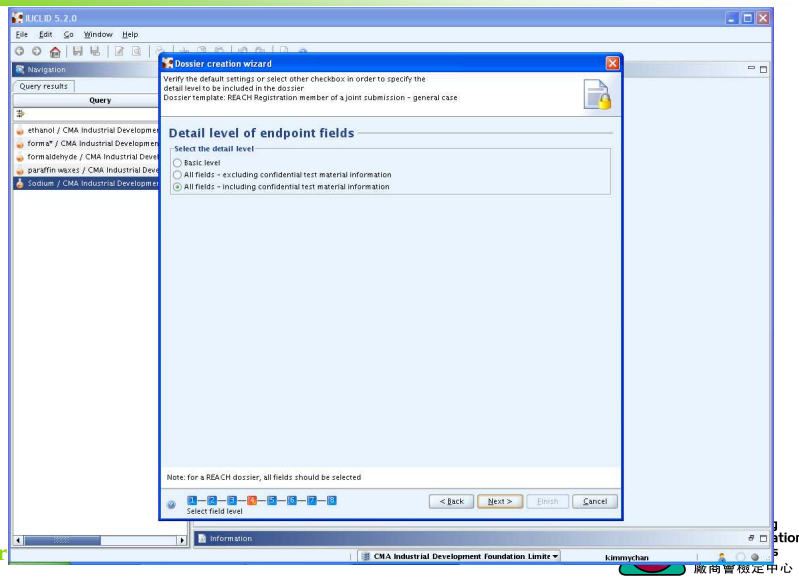




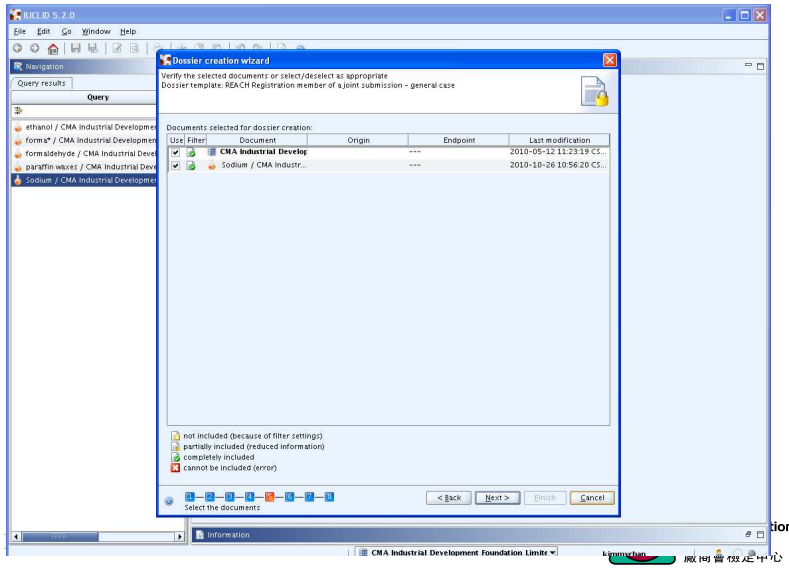

# Dossier output page 3



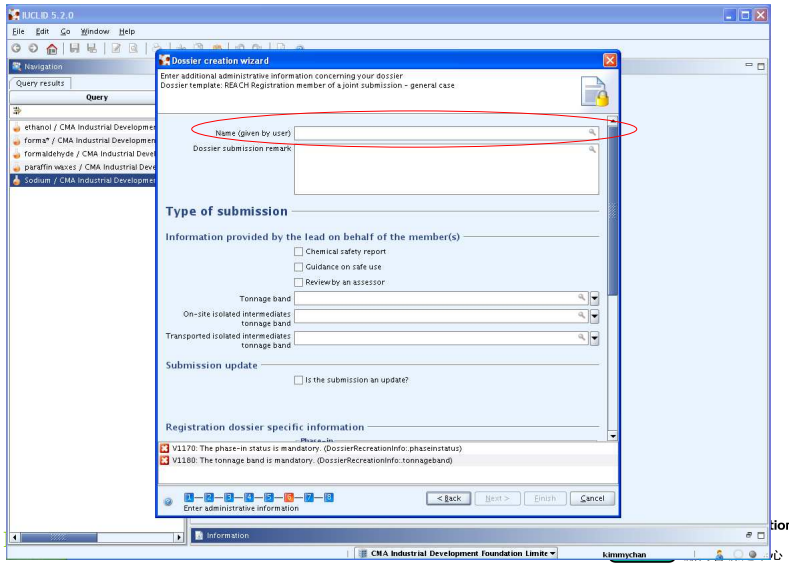
# Dossier output page 4


IUCLID 5.2.0
Dossier creation wizard
Detail level of endpoint fields
Basic level
All fields - excluding confidential test material information
All fields - including confidential test material information
Note: for a REACH dossier, all fields should be selected
< Back
Next >
Finish
Cancel

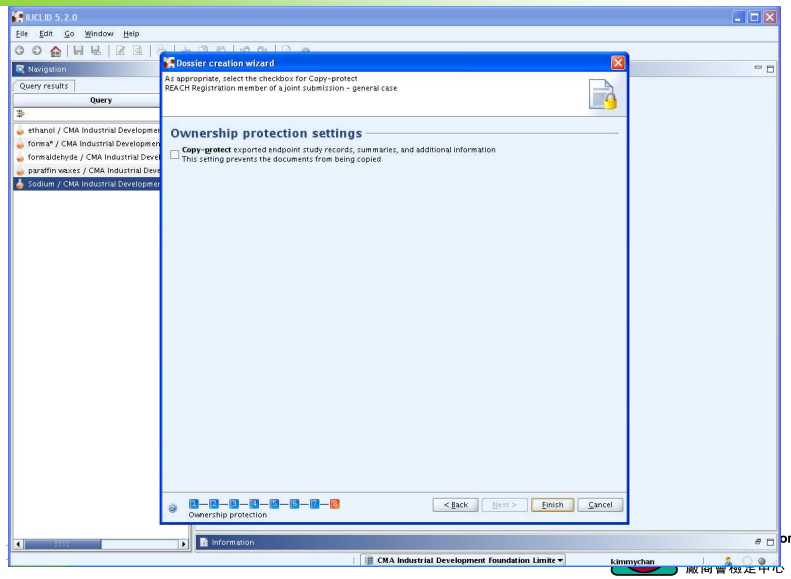
# Dossier output page 5



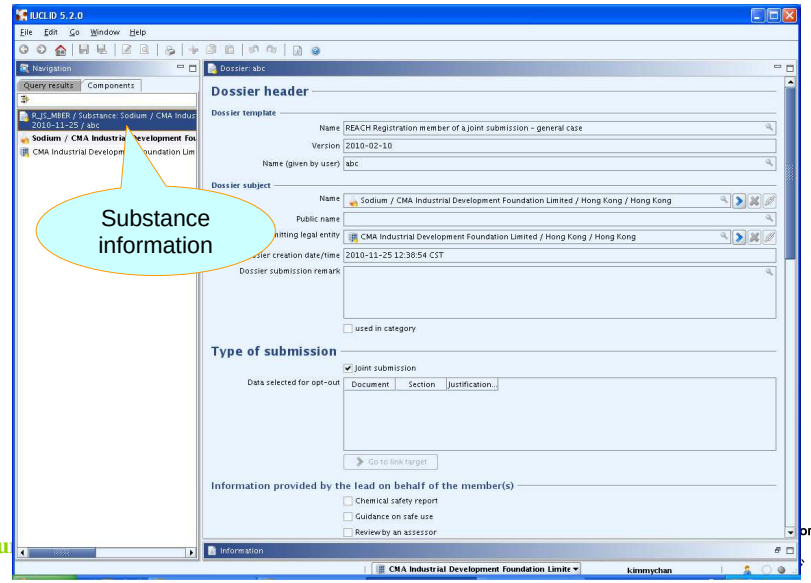

# Dossier header




# Dossier output page 7

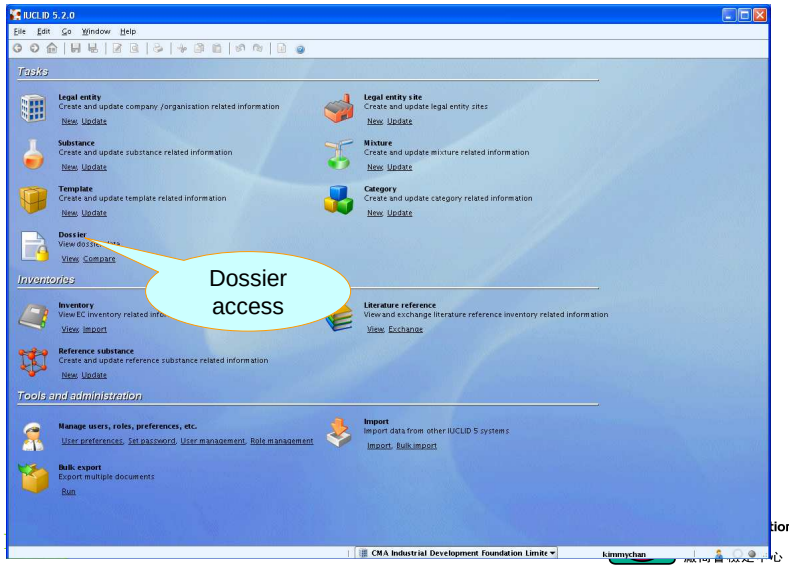


# Checking dossier



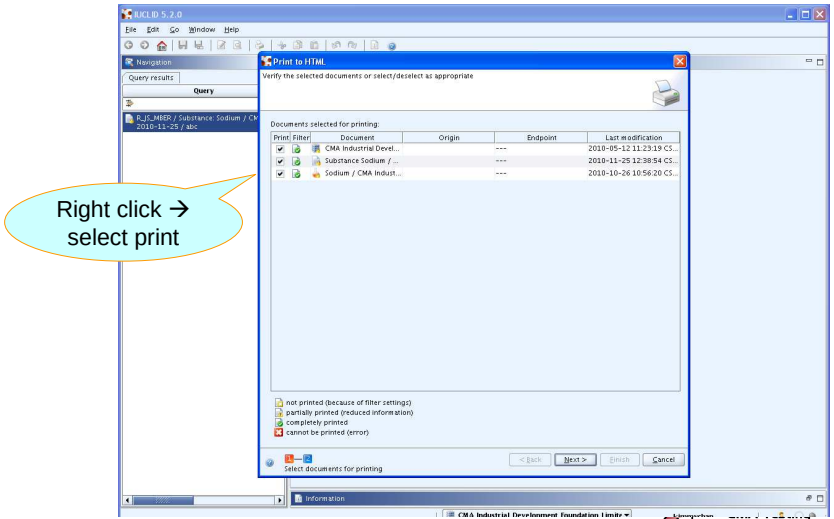



# Accessing the dossier from the front page






# Printing to html



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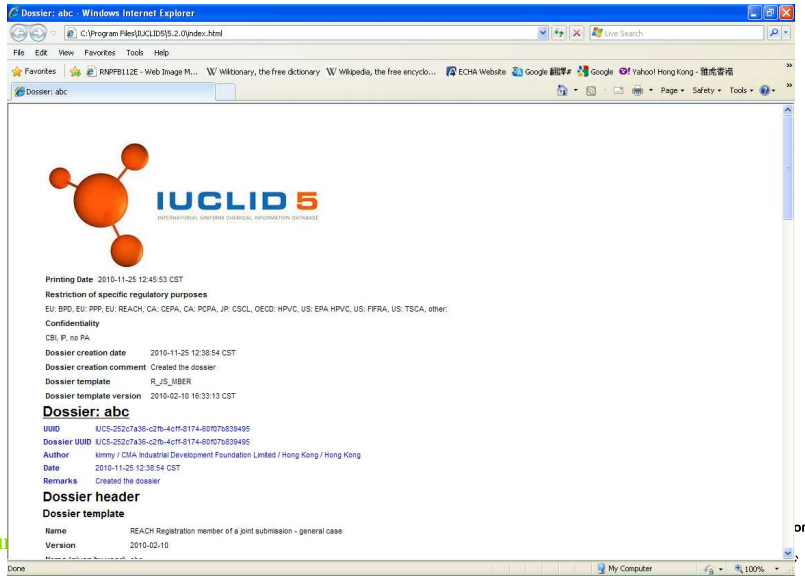
# Output file – front page



# Agenda

- Preparing a registration dossier with IUCLID 5
- **Import – Export**
- Advanced tools
- Submit a dossier



# Import - Export

- **Import – Export**
  - Export
  - Import
  - Migration tool

Your Reliable Quality Solution Partner

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# Import

- **Import is possible for:**
  - Substance data
  - Single element (e.g. Legal entity, single endpoint)
  - Dossiers
  - Reference Substances
  - EC inventory

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# Export

- **Export is possible for:**
  - Substance data
  - Single elements (e.g. Legal entity, single endpoint)
  - Dossiers
  - Reference Substances

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# Export

- The Export function consists of a number of steps depending on what is exported
- Such steps allow to filter the exported information, define its protection level or allow to add comments
- Export is possible for a single data set or for a single substance, bulk export is not possible
- The Export command can be executed in two ways:
  - By right-clicking on the endpoint record of choice
  - By clicking on the export command on the file menu on the menu bar



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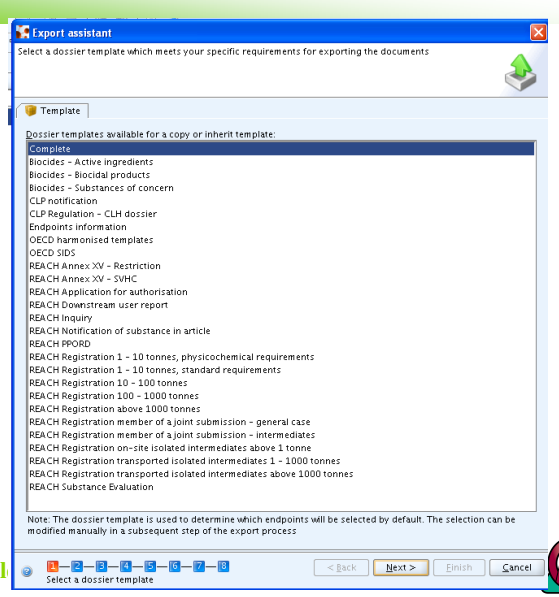
# Export – Step 1


Export assistant
Select a dossier template which meets your specific requirements for exporting the documents
Template
Dossier templates available for a copy or inherit template:
Complete
Biocides - Active ingredients
Biocides - Biocidal products
Biocides - Substances of concern
CLP notification
CLP Regulation - CLH dossier
Endpoints information
OECD harmonised templates
OECD SIDS
REACH Annex XV - Restriction
REACH Annex XV - SVHC
REACH Application for authorisation
REACH Downstream user report
REACH Inquiry
REACH Notification of substance in article
REACH PPORD
REACH Registration 1 - 10 tonnes, physicochemical requirements
REACH Registration 1 - 10 tonnes, standard requirements
REACH Registration 10 - 100 tonnes
REACH Registration 100 - 1000 tonnes
REACH Registration above 1000 tonnes
REACH Registration member of a joint submission - general case
REACH Registration member of a joint submission - intermediates
REACH Registration on-site isolated intermediates above 1 tonne
REACH Registration transported isolated intermediates 1 - 1000 tonnes
REACH Registration transported isolated intermediates above 1000 tonnes
REACH Substance Evaluation
Note: The dossier template is used to determine which endpoints will be selected by default. The selection can be modified manually in a subsequent step of the export process
Select a dossier template
< Back
Next >
Finish
Cancel



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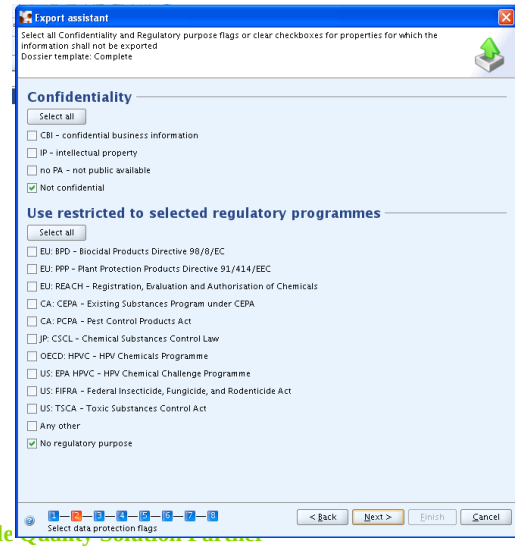
# Export – Step 2


Export assistant
Select all Confidentiality and Regulatory purpose flags or clear checkboxes for properties for which the information shall not be exported
Dossier template: Complete
Confidentiality
Select all
CBI - confidential business information
IP - intellectual property
no PA - not public available
Not confidential
Use restricted to selected regulatory programmes
Select all
EU: BPD - Biocidal Products Directive 98/8/EC
EU: PPP - Plant Protection Products Directive 91/414/EEC
EU: REACH - Registration, Evaluation and Authorisation of Chemicals
CA: CEPA - Existing Substances Program under CEPA
CA: PCPA - Pest Control Products Act
JP: CSCL - Chemical Substances Control Law
OECD: HPVC - HPV Chemicals Programme
US: EPA HPVC - HPV Chemical Challenge Programme
US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
US: TSCA - Toxic Substances Control Act
Any other
No regulatory purpose
Select data protection flags
< Back
Next >
Finish
Cancel



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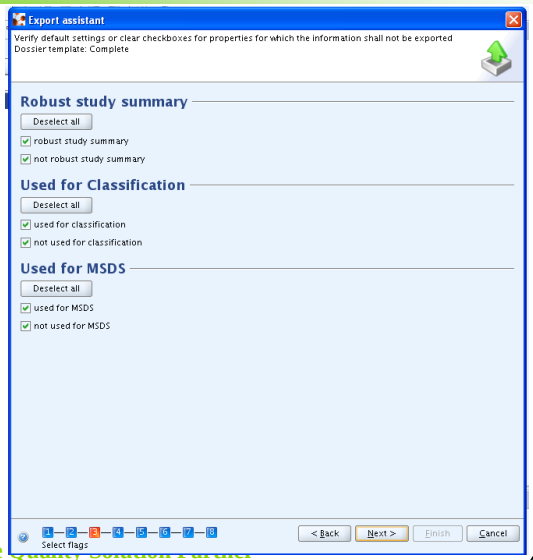
# Export – Step 3



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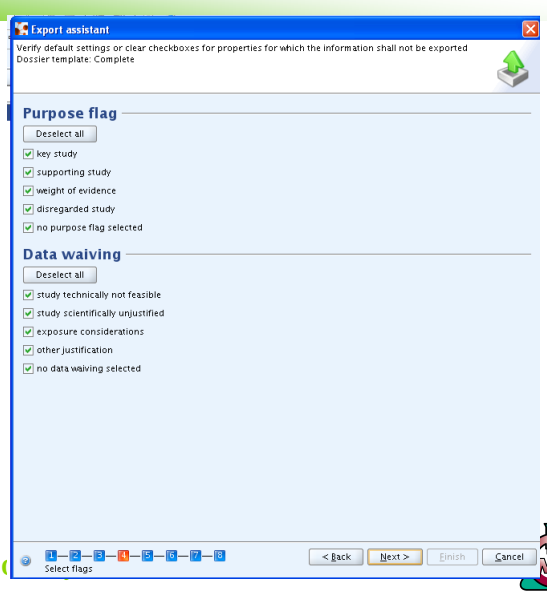
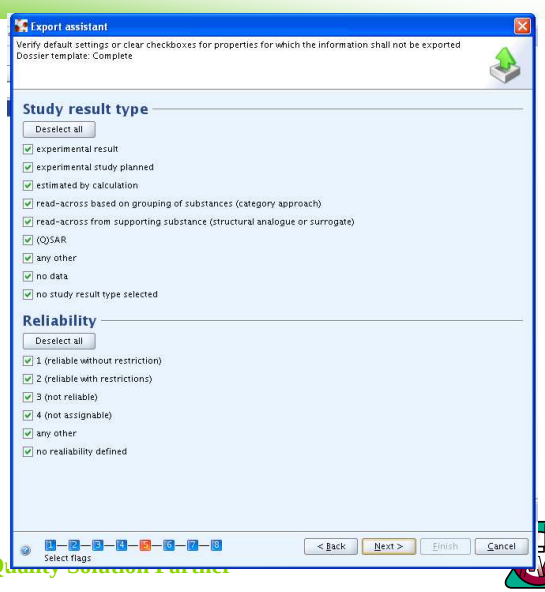
# Export – Step 4



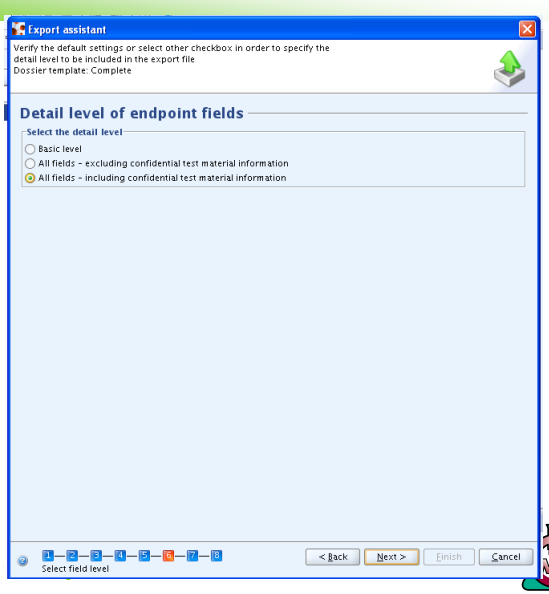



# Export – Step 5



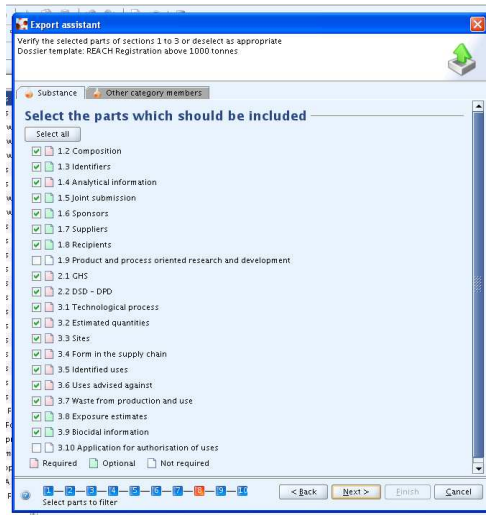



# Export – Step 6

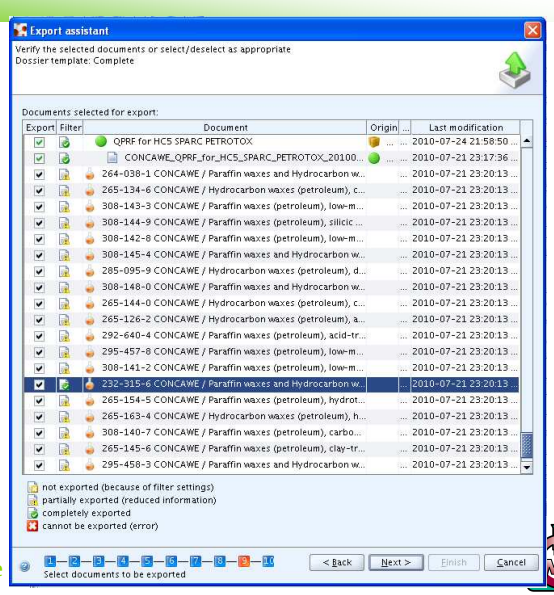

Export assistant
Verify the default settings or select other checkbox in order to specify the detail level to be included in the export file
Dossier template: Complete
Detail level of endpoint fields
Select the detail level
Basic level
All fields - excluding confidential test material information
All fields - including confidential test material information
Select field level
< Back
Next >
Finish
Cancel



# Export – Step 7



# Export – Step 8



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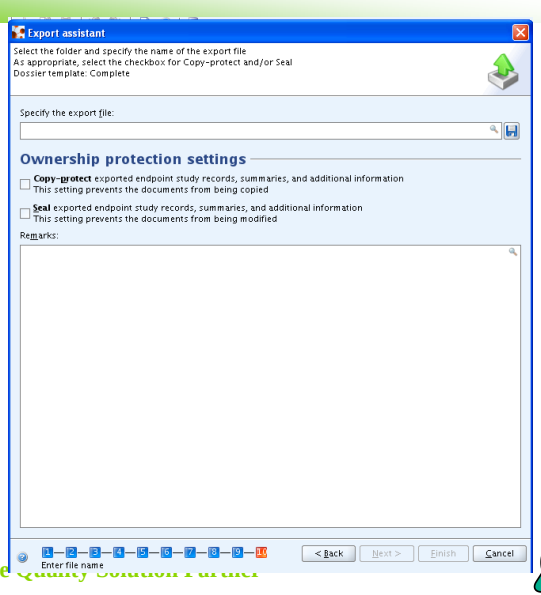
# Export – Step 9


Export assistant
Select the folder and specify the name of the export file
As appropriate, select the checkbox for Copy-protect and/or Seal
Dossier template: Complete
Specify the export file:
Ownership protection settings
Copy-protect exported endpoint study records, summaries, and additional information
This setting prevents the documents from being copied
Seal exported endpoint study records, summaries, and additional information
This setting prevents the documents from being modified
Remarks:
Enter file name
< Back
Next >
Finish
Cancel



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# Agenda

- Preparing a registration dossier with IUCLID 5
- Import – Export
- **Advanced tools**
- Submit a dossier



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# Advanced Tools

- Templates
- Categories
- Plug-ins
  - Bulk Export Plug-in
  - Migration tool
  - Pre-registration Plug-in
  - SNIF Migration tool
  - Query Plug-in
  - Helpsystem Plug-in
  - CSR Plug-in
  - Technical Completeness Tool



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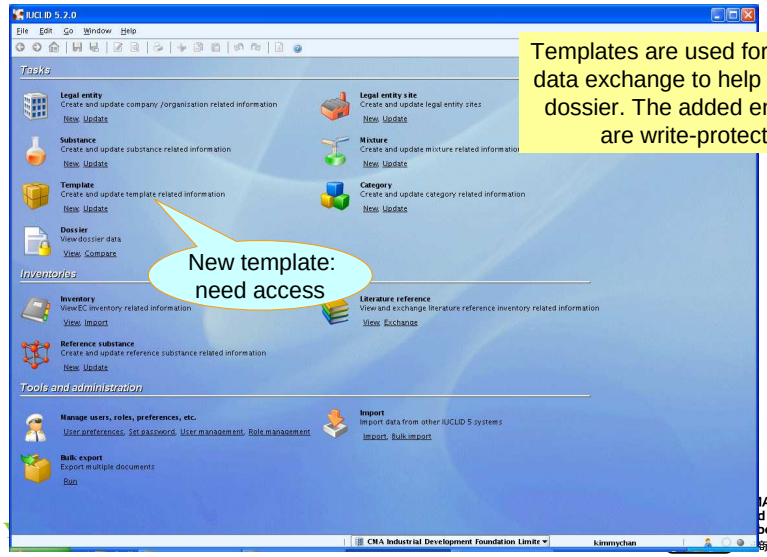
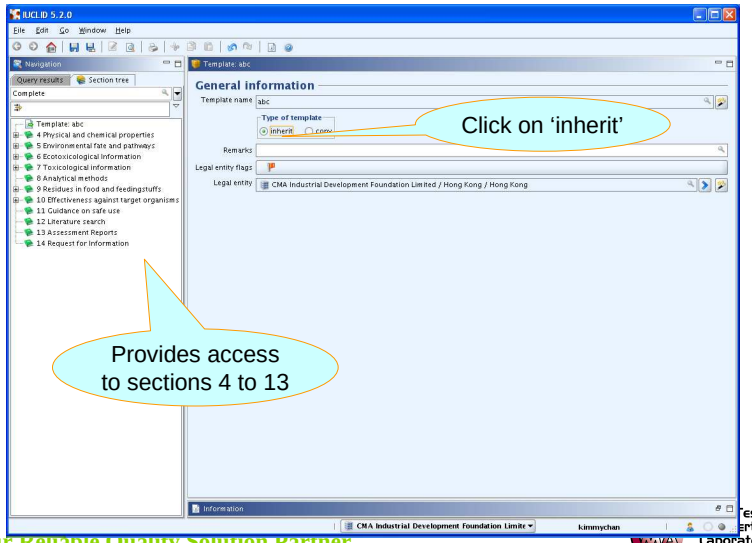
# Templates


Templates are used for end point data exchange to help compile a dossier. The added end points are write-protected.
New template: need access

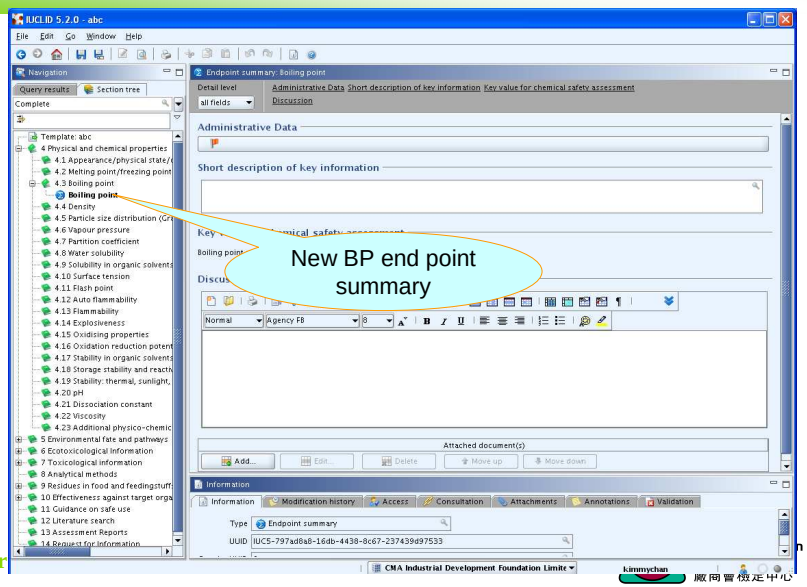


# Create an ‘inherit’ template



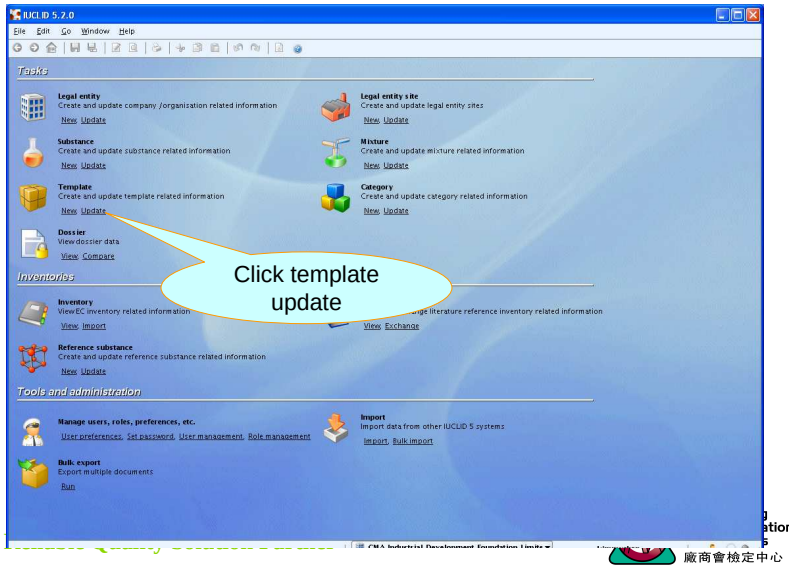



# Add substance data – sections 4 - 13

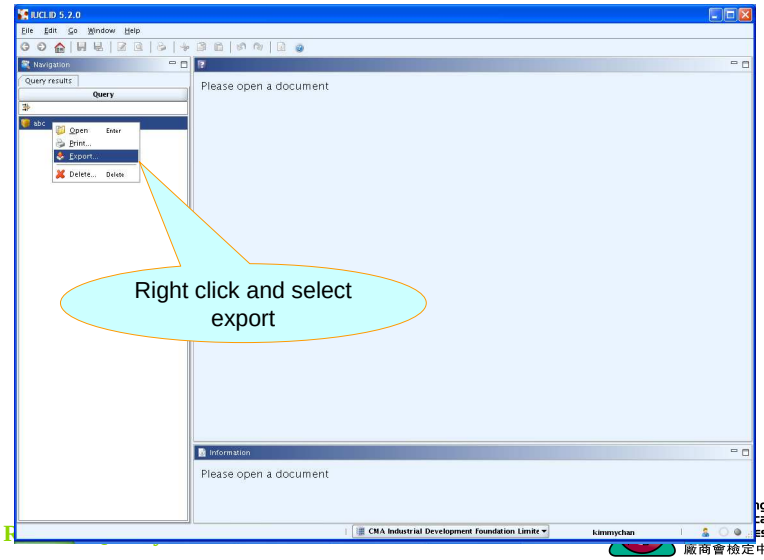





# View template from front page

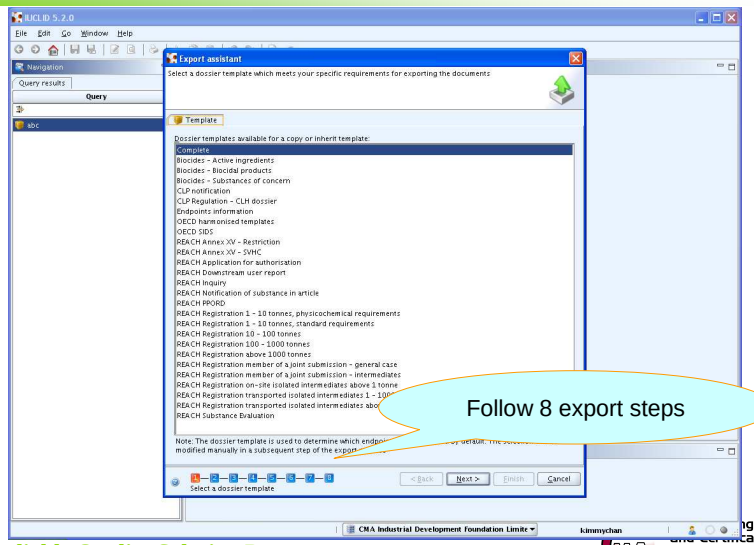


# Export template



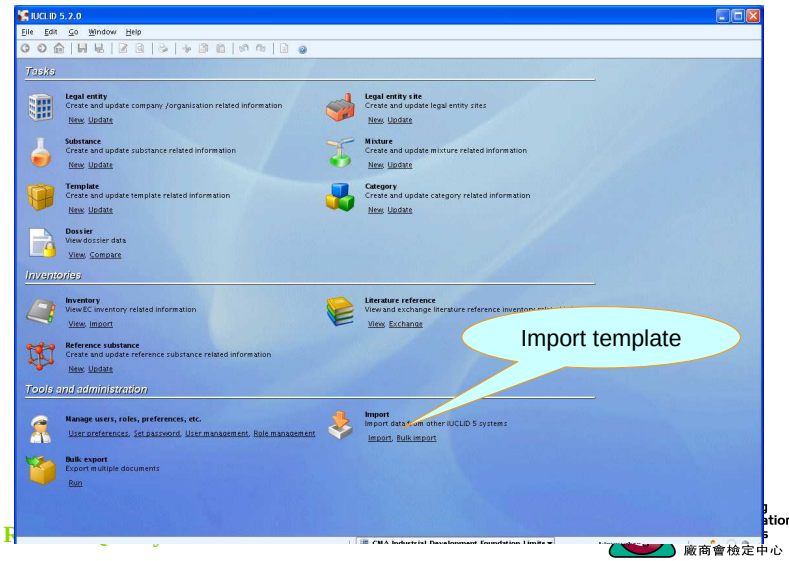



# Add data from template


IUCLID 5.2.0
Export assistant
Select a dossier template which meets your specific requirements for exporting the documents
Template
Dossier templates available for a copy or inherit template:
Complete
Biocides – Active ingredients
Biocides – Biocidal products
Biocides – Substances of concern
CLP notification
CLP Regulation – CLH dossier
Endpoints information
OECD harmonised templates
OECD SIDS
REACH Annex XV – Restriction
REACH Annex XV – SVHC
REACH Application for authorisation
REACH Downstream user report
REACH Inquiry
REACH Notification of substance in article
REACH PPORD
REACH Registration 1 – 10 tonnes, physicochemical requirements
REACH Registration 1 – 10 tonnes, standard requirements
REACH Registration 10 – 100 tonnes
REACH Registration 100 – 1000 tonnes
REACH Registration above 1000 tonnes
REACH Registration member of a joint submission – general case
REACH Registration member of a joint submission – intermediates
REACH Registration on-site isolated intermediates above 1 tonne
REACH Registration transported isolated intermediates 1 – 10
REACH Registration transported isolated intermediates abo
REACH Substance Evaluation
Select a dossier template
< Back
Next >
Finish
Cancel
CMA Industrial Development Foundation Limite
kimmychan
Follow 8 export steps

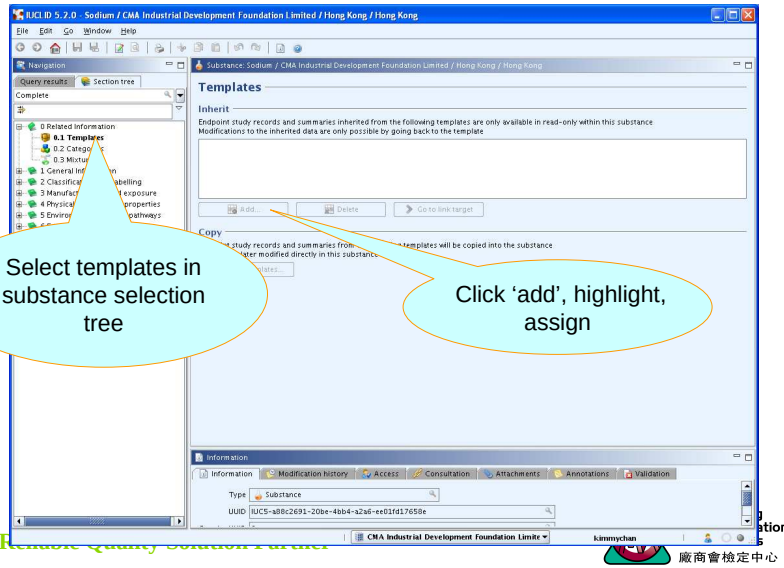


# Import template






# Add data from template



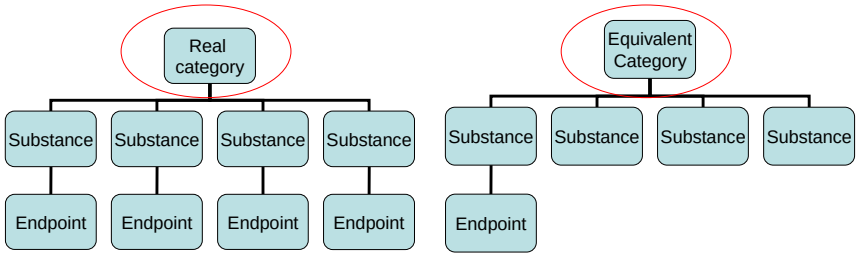
# Categories

- A chemical category is a group of chemicals whose physicochemical and toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity.
- A chemical category is defined by a list of chemicals (the category members) and by a set of properties and/or effects for which experimental and or estimated data are available or can be generated (the category endpoints). A chemical category can be represented in the form of a matrix.
- Data gaps in a chemical category can be filled by using various approaches, including simple read-across, trend analysis (interpolation and extrapolation) and computational methods based on SARs, QSARs.



# Categories

- Real categories – group of similar chemical substances, used to identify and fill data gaps across the members of the category
- 'Equivalent substances' category – used to group chemicals sharing the same information over a number of end points.






# Bulk export tool

- The purpose of the Bulk Export tool is to allow a set of documents to be exported in bulk. With this ply-in you can, for example, export all the substance datasets available in your IUCLID database, at once.
- Another example is to export in one go, all the dossiers for a given substance. The user manual can be downloaded from the Get Support/ Documentation section of the IUCLID website.



# Query Plug-in

- The IUCLID 5 Query Tool provides easy access to predefined sets of business-relevant information by extending the ways in which data can be queried in the IUCLD 5 database.

# CSR Plug-in

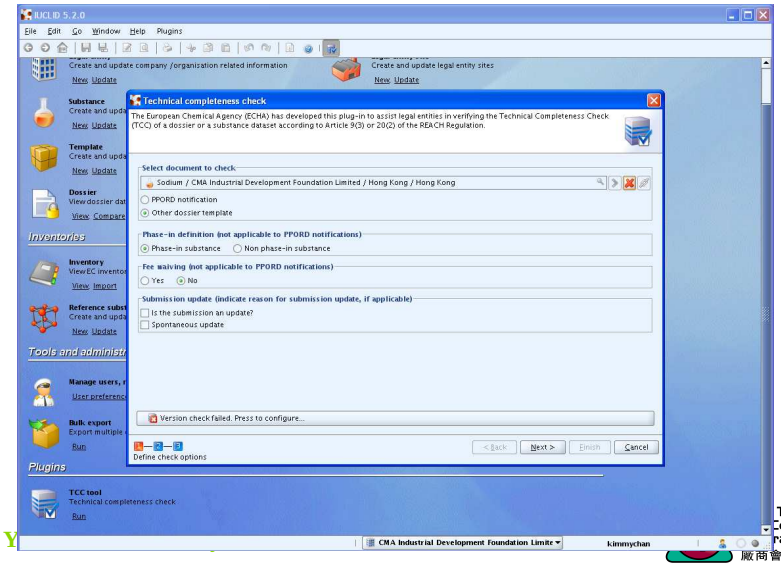
- The IUCLID 5 CSR plug-in extracts data from a IUCLID 5 data set or dossier in order to prepare the Chemical Safety Report (CSR). The detailed user manual can be downloaded from the Get Support/ Documentation section of the IUCLID website.



# Technical Completeness Tool

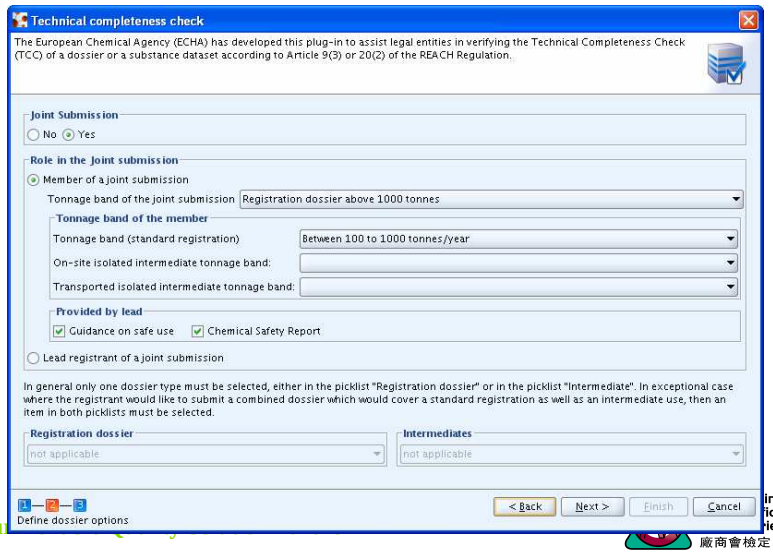
- The aim of the Technical Completeness Check (TCC) plug-in is to enable registrants and PPORD notifiers to check within their IUCLID installation (or database) the technical completeness of their dossiers (or datasets) prior a submission to ECHA via REACH-IT. The plug-in also checks that the dossier (or substance) will be able to pass some of the business rules that can be found in REACH-IT.

# Technical Completeness Tool

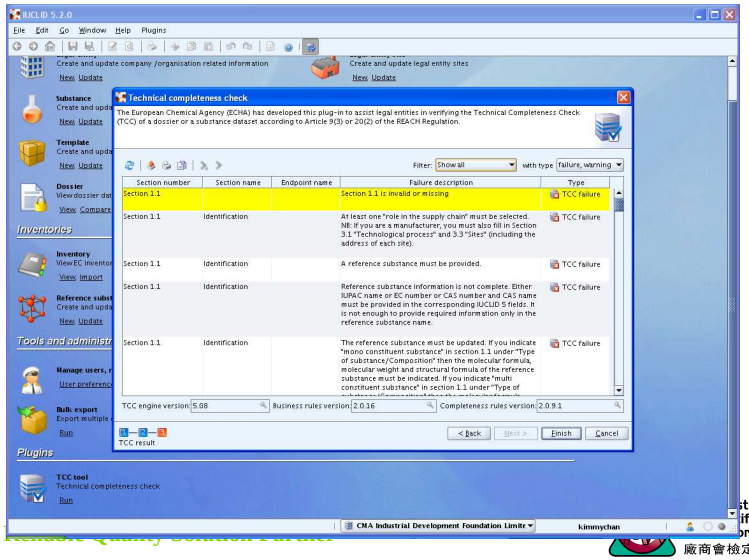

IUCLID 5.2.0
File Edit Go Window Help Plugins
Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Select document to check
Sodium / CMA Industrial Development Foundation Limited / Hong Kong / Hong Kong
PPORD notification
Other dossier template
Phase-in definition (not applicable to PPORD notifications)
Phase-in substance
Non phase-in substance
Fee waiving (not applicable to PPORD notifications)
Yes
No
Submission update (indicate reason for submission update, if applicable)
Is the submission an update?
Spontaneous update
Version check failed. Press to configure...
Define check options
< Back
Next >
Finish
Cancel
Inventories
Tools and administra
Plugins
TCC tool
Technical completeness check
Run
CMA Industrial Development Foundation Limite
kimmychan



# Technical Completeness Tool


Technical completeness check
The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.
Joint Submission
No
Yes
Role in the Joint submission
Member of a joint submission
Tonnage band of the joint submission
Registration dossier above 1000 tonnes
Tonnage band of the member
Tonnage band (standard registration)
Between 100 to 1000 tonnes/year
On-site isolated intermediate tonnage band:
Transported isolated intermediate tonnage band:
Provided by lead
Guidance on safe use
Chemical Safety Report
Lead registrant of a joint submission
In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.
Registration dossier
not applicable
Intermediates
not applicable
Define dossier options
< Back
Next >
Finish
Cancel

# Technical Completeness Tool



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# Agenda

- Preparing a registration dossier with IUCLID 5
- Import – Export
- Advanced tools
- **Submit a dossier**



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# Lead versus member dossier

- **Lead dossier**
  - All the requirements for the highest tonnage band within the joint submission
- **Member dossier**
  - Only limited information needed: identification of company and substance and information on manufacture and uses
  - Other information included in the dossier will be regarded as an opt-out



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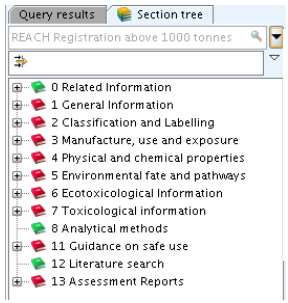
# Lead versus member dossier

**Lead**

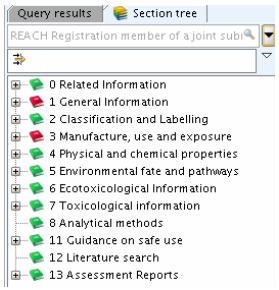



Private data submitted by the LEAD and the MEMBER

Data submitted only by the LEAD (if not opted-out)

Data submitted either by the LEAD or individually

**Member**



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# Creating the lead dossier

- **Critical elements dataset**
  - Legal entity
  - Substance composition
  - Endpoint study records
  - Chemical safety report and guidance on safe use
- **Use the TCC plug-in on your substance dataset**
  - You will be alerted of any lack of data
  - It also checks most of the business rules



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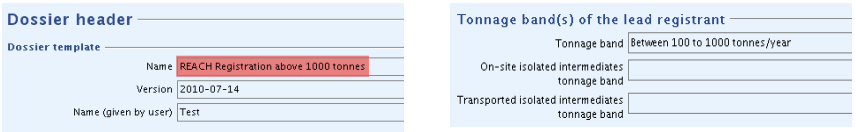
# Creating the lead dossier

- **Create your dossier**
  - Tonnage band of joint submission: dossier template
  - Own tonnage band: indicated in dossier header
    - Basis for invoice




- **Use Dissemination and Fee calculation plug-in on dossier**
- **Also run again the TCC plug-in on your dossier**



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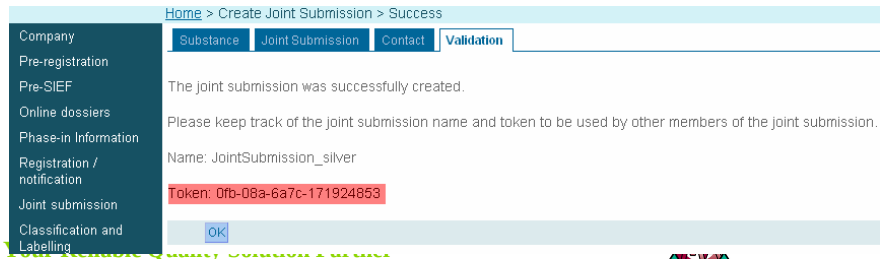
# Create the Joint Submission Object

- **Create JSO before submitting the lead dossier**
- **Easy process. Follow the wizard**
  - Identify substance
  - Give it a name
  - Select contact person
- **Once created you will receive a 'token'**

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# Distributing the token

- **It is the responsibility of the lead to communicate the token to the members of the joint submission**
  - It has to be done outside REACH-IT
- **Members need the token to join the joint submission**
- **Once joined, a member does not need the token anymore**
- **The lead can generate a new token at any time**



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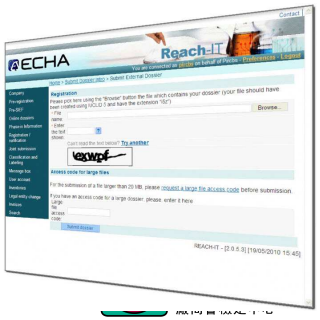
# Submit

- **The lead can submit the registration dossier as soon as the joint submission has been created in REACH-IT**
- **The dossier will go through a series of preliminary checks:**
  - Virus check
  - File format validation
  - Business rules

IUCLID .i5z
Dossier submission






# What if lead fails business rules?

- **Business rules are a set of administrative checks ensuring that ECHA has enough information to be able to process the dossier**
- **Most critical step in your registration process**
  - Your dossier has to successfully pass before the deadline
  - Prepare your submission well in advance of the deadline



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# What if lead fails business rules?

- **In case of a business rule failure:**
  - Your dossier is not accepted for processing
  - You will be informed through a message in REACH-IT with details on the failure and instructions
- **The lead will have to modify the dossier accordingly**
  - Follow the instructions in the error message
  - Consult the specific manual on business rules failures
  - Contact relevant helpdesk for assistance if needed
- **Members will not be able to submit until after the lead has passed business rules**



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# Member dossier

- **Critical elements**
  - Legal entity
  - Substance composition
  - Indicate whether lead is submitting CSR on your behalf or not
- **Does the lead submit the CSR and/or Guidance on Safe use on your behalf?**



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# Member dossier

- **Use the TCC plug-in on your substance dataset**
- **Use Dissemination and Fee calculation plug-in on dossier**
- **Run the TCC plug-in again on your dossier**



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# Submit

- **Before submitting, members have to join the joint submission in REACH-IT**
- **Members can submit as soon as the lead has passed business rules**
  - Members can follow the status of the lead dossier in REACH-IT

IUCLID .i5z
Dossier submission

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# What if member fails business rules?

- **Most critical step in your registration process**
  - Prepare your submission in advance of the deadline
- **In case of a business rule failure:**
  - Your dossier is not accepted for processing
  - You will be informed through a message in REACH-IT with details on the failure and instructions



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# For all submissions: company size!

- **SMEs benefit from a fee reduction in both the REACH and CLP regulations;**
- **Company size will determine the invoice**
  - Also ownership, voting rights and relationships with other companies contribute to determining a company size
  - Only Representatives (OR) should make sure that your registration is in line with the size of the company you represent



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# For all submissions: company size!

- **Make sure it is correct in REACH-IT before you submit**

- **ECHA has the responsibility to check the size of the companies who are eligible for REACH and CLP rebates**



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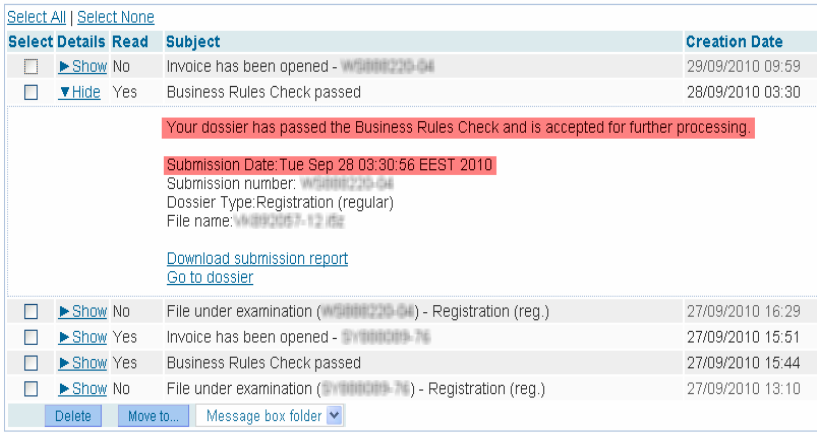
# Confirmation of submission


Select All | Select None
Select Details Read Subject Creation Date
Show No Invoice has been opened - 29/09/2010 09:59
Hide Yes Business Rules Check passed 28/09/2010 03:30
Your dossier has passed the Business Rules Check and is accepted for further processing.
Submission Date:Tue Sep 28 03:30:56 EEST 2010
Submission number:
Dossier Type:Registration (regular)
File name:
Download submission report
Go to dossier
Show No File under examination ( ) - Registration (reg.) 27/09/2010 16:29
Show Yes Invoice has been opened - 27/09/2010 15:51
Show Yes Business Rules Check passed 27/09/2010 15:44
Show No File under examination ( ) - Registration (reg.) 27/09/2010 13:10
Delete
Move to...
Message box folder



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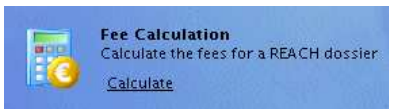
# Checklist #1 Invoicing and fee payment

- **Invoice will be sent once dossier has been accepted**
  - Initial payment due date is indicated in invoice
  - If payment not received, due date will be automatically extended
- **Use "Fee calculation' plug-in before submitting your dossiers**
- **Make arrangements with your accounting department**



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# Checklist#1 Invoicing and fee payment

- **Registration number cannot be issued before payment is received**
- **Ensure payment is made within extended due date**
  - Otherwise the registration will be rejected



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# Checklist#1 Invoicing and fee payment

- **Ensure a quick confirmation that the payment is successful by following these best practices:**
  - Reference number (=invoice number) in the free text payment message field → 8 digits
  - Single payment (one invoice per payment transaction)
  - SEPA (Single Euro Payments Area) payment
  - Pay exactly the invoiced amount
- **This enables the automatic treatment of your payment once it has been received by ECHA**



# Checklist#1 Invoicing and fee payment

- **Prepare your accounting department for ECHA's invoices**
  - You can create ECHA as a client in your accounting system before receiving ECHA's invoices
- **Updated Frequently Asked Questions on invoicing and payments are available in our website**
  - They contain detailed advice for registrants and their accounting department on ECHA's invoicing and management of payments

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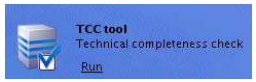
# Checklist#2 Technical completeness check

- **Use "TCC tool' plug-in before submitting your dossiers**
  - 'TCC tool' also includes most of business rules checks
  - Run the tool on your substance dataset
  - But also after creating your dossier




- **Same tool is used at ECHA to check your dossiers**

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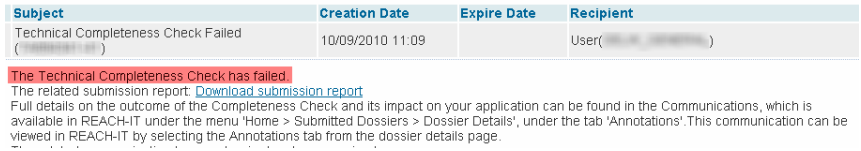
# Checklist#2 Technical completeness check

- **In case of completeness check failure:**
  - You will receive a message in REACH-IT
  - The message links to a letter with detailed list of failures and instructions on how to resubmit
  - ECHA will set a reasonable deadline
  - You remain legally on the market



| Subject | Creation Date | Expire Date | Recipient |
|---|---|---|---|
| Technical Completeness Check Failed ( ) | 10/09/2010 11:09 | | User( ) |

The Technical Completeness Check has failed.
The related submission report: Download submission report
Full details on the outcome of the Completeness Check and its impact on your application can be found in the Communications, which is available in REACH-IT under the menu 'Home > Submitted Dossiers > Dossier Details', under the tab 'Annotations'.This communication can be viewed in REACH-IT by selecting the Annotations tab from the dossier details page.

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# Checklist#2 Technical completeness check

- **How should you react after a TCC failure:**
  - Ensure that you correct all the sections that were indicated as failing in the communication letter
  - Run the “TCC tool” plug-in
  - Contact relevant helpdesk for assistance if needed
  - Resubmit the complete dossier before the deadline set by ECHA



# Checklist#3 Receiving the registration number

- **ECHA will issue the registration number when:**
  - Your dossier is considered technically complete, and
  - The fee payment has been received in full
- **You will receive the Decision letter containing your registration number through REACH-IT**



# Checklist#3 Receiving the registration number

ECHA
European Chemicals Agency

**CompanyName**
Street
Street2
PostalCode, Town
Country

Helsinki, Today

Submission date: **SubmissionDate**
Submission number: **SubmissionNumber**
Decision number: **CommunicationNumber**

**DECISION ON YOUR REGISTRATION UNDER REGULATION (EC) NO 1907/2006**

Dear Sir/Madam,

In accordance with Article 20(2) of Regulation (EC) No 1907/2006 (“the REACH Regulation”), the European Chemicals Agency (ECHA) has concluded the completeness check of your registration dossier for **SubstanceName**. This registration by **CompanyName** includes:

- a substance in quantities **TonnageBand**
- a transported isolated intermediate, according to Article 18 of the REACH Regulation, in quantities **TOSIITonnageBand**
- an on-site isolated intermediate, according to Article 17 of the REACH Regulation, in quantities **OSIITonnageBand**

The registration was considered complete.

The registration number for this registration: **ReferenceNumber**

The registration date for this registration: **ReferenceDate**

This registration entitles you to manufacture/import this substance (or, if relevant, use in the production of articles). If, however, you have been informed by ECHA that a previous registrant has requested a 4-month extension of your waiting period, you may only start to manufacture/import (or use) the substance 4 months from the date of this decision.



# Checklist#4 Dissemination

- **Information from your registration dossier will be disseminated on the ECHA website**
- **Certain information can be claimed confidential**
- **Confidentiality claims must be justified**
  - Confidentiality Justification Template
- **Tools are available to determine which information will be disseminated:**
  - Manuals on the ECHA website (DSM 15 & 16)
  - IUCLID dissemination plug-in

# Checklist#5 Updating your registration

- **You need to keep your registration updated**
  - Any change in composition of the substance
  - Change of tonnage band
  - New identified uses
  - Changes in the classification and labelling
  - Etc
- **Therefore sufficient REACH resources need to be maintained**



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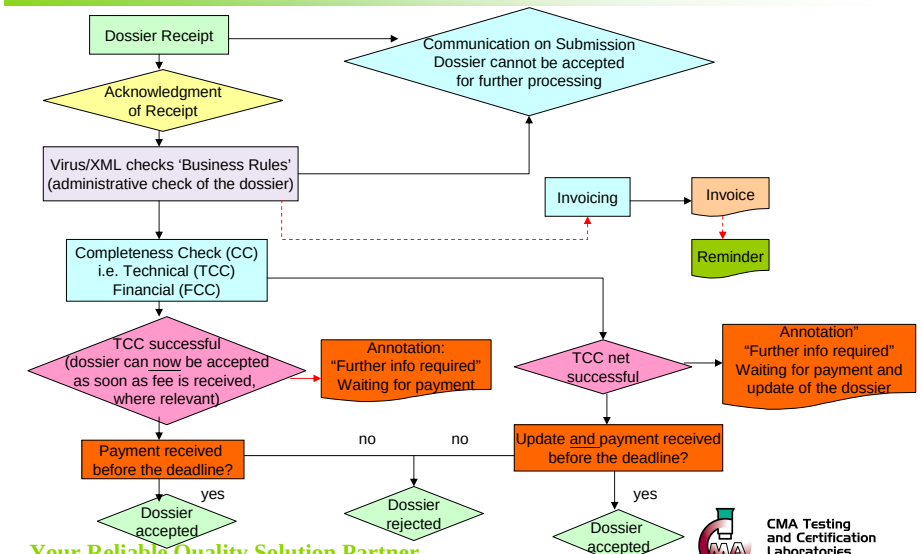
# Post-submission



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# Thank you.



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